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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,048	08/17/2001	Tadashi Okamoto	35.G2025 Div.I	3284

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NEW YORK, NY 10112

EXAMINER

MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,048

Applicant(s)

OKAMOTO ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 13 and 186 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-10, 12, 13 and 186 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 11/8/04, have been fully considered and they are deemed to be persuasive to overcome the previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

The amendment, filed 11/8/04, has been entered.

Due to the newly applied rejections, summarized below, the finality of the Office action, mailed 5/4/04, is hereby withdrawn.

Further, due to the overcoming of the rejections of record and newly applied rejections, the Notice of Appeal, filed 11/8/04, is also deemed moot.

Yet further, the specie election requirement, elected on 7/25/03 by applicants, is hereby withdrawn due to the above noted overcoming of rejections of record. Thus, all compound specie embodiments of the pending claims are now under examination.

VAGUENESS AND INDEFINITENESS

Claims 1-10, 12, 13, and 186 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 1-2, the claimed process is directed to detecting a target single-stranded nucleic acid which is indicative of the detection of said target... per se. Consideration of the actual claim steps reveals that none of the steps set forth such detection. Rather a double stranded nucleic acid is formed etc. with detection via

luminescence after providing a chemiluminescent compound but no specificity regarding said target single-stranded nucleic acid as in the preamble of claim 1. There is no stringency of hybridization in the claim. There is no definition of the metes and bounds of complementary practice in line 5 of claim 1 as to whether this is 100% complementary, 90%..., 50%..., 10%..., etc. complementary. Less than 100% complementarity is well known for hybridization probe practice in hybridization assays. Therefore, it is unclear whether the preamble controls the metes and bounds of the claim or the actual claim steps which, in conflict, lack specificity limitations regarding detection of said target single-stranded nucleic acid. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from claim 1 also contain this unclarity due to their dependence.

In claim 1, line 9, the detection of luminescence is set forth. Luminescence is a generic term that is reasonably interpreted to include more than chemiluminescence. For example, photoluminescence is a type of luminescence but is not chemiluminescence. An unclarity as to metes and bounds is the contrasting citation of providing a chemiluminescent compound in line 6 of claim 1 but detecting it in line 9 via luminescence. This inconsistency causes claim 1 and those dependent therefrom to be vague and indefinite. Similarly, claim 2, lines 3-4, cites the exhibiting of chemiluminescence which contrasts with the "luminescence-detecting step" citation in line 2 therein. Clarification via clearer claim wording is requested.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) and (e)(2) as being clearly anticipated by Bieniarz et al.. (P/N 5,599,932).

The title and abstract of the reference directs the invention therein disclosed to intercalator practice. The usage of such intercalator compounds in the invention for detection of DNA hybridization is described in column 8, lines 25-28. The hybridization of a probe to target single-stranded nucleic acid to form a double-stranded hybrid is exemplified in Examples 24-28 in columns 41-44 as also required in instant claim 1, lines 3-5. The specific usage of an intercalator/chemiluminescent compound for such double-stranded nucleic acid hybrid detection is set forth in columns 49-50 as Example 39 wherein the practice therein anticipates the limitations of lines 6-12 of instant claim 1. The intercalator/chemiluminescent compound is a conjugate as described in said Example 39 which is a covalent compound which reads on the chemiluminescent compound of instant claim 1. The washing away of unbound conjugate in said Example

39 results in meeting the requirements of instant claim 2. Applicants are reminded that there has been no filing of priority documents nor with certified translations regarding the instant application thus resulting in no priority grant earlier than the filing date of the parent application of 10/2/97 thus supporting the above stated rejection under 35 U.S.C. 102(a).

Claims 1-6 and 10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Xu et al. [J. Am. Chem. Soc. 117:2627 (1995)].

In the title and abstract Xu et al. discloses the chemiluminescent detection of DNA hybridization. On page 2628 in Figure 1 the same process of single-stranded DNA detection is shown as in instant claim 1. A probe/target hybrid is formed, an ECL (chemiluminescent compound) is provided which intercalates to the double-stranded DNA hybrid and is detected via ECL, luminescence. This is further detailed on page 2629, first column, second full paragraph, and anticipates the above listed instant claims. Yet another detailed description of this process is set forth in the reference on page 2630 in the section entitled "Immobilization and Hybridization of Poly(dA) and Poly(dT)" which includes a discussion that only the double-stranded associated chemiluminescent compound in an aqueous solution is detected as required in instant claims 2 and 3. The aqueous medium being water as well as buffered as instant claims 4 and 5 is set forth in the reference in the section entitled "Chemicals and Materials" on page 2628 of the reference wherein deionized water is utilized as described therein. This section on page 2628 also discloses the tripropylamine organic solvent content of

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the ECL buffer as also required in instant claim 6 via is miscible organic solvent limitation. The pH of 7 in this page 2628 section also anticipates instant claim 10.

OBVIOUSNESS-TYPE DOUBLE PATENTING

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 12, 13, and 186 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 13, 14, and 22 of U.S. Patent No. 5,624,798 (already of record). Although the conflicting claims are not identical, they are not patentably distinct from each other because common process embodiments are present in each claim set. In claims 5 and 6 of said Patent a double stranded hybrid of nucleic acids is formed via hybridization between complementary probe or primer and target nucleic acid as also practiced in the above listed instant claims. The compounds in the Patent claims are directed to the same compound as in instant claims 12, 13, and 186 as cited therein as well as in claims 1 and 2 of the Patent thus carrying the same chemiluminescence character due to the identical chemical

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structures. The pyrylium compounds of the Patent claims intercalate into double-stranded nucleic acid as also practiced in the instant claims and are detected by fluorescence which is a type of luminescence as cited for detection in instant claim 1, lines 9-10. As noted in the above rejection under 35 U.S.C. 112, second paragraph, the instant claims may be interpreted as not requiring single-stranded target detection as only cited in the preamble of instant claim 1 due to the actual claim steps in instant claim 1 only forming a double stranded nucleic acid with detection thereof via chemiluminescent compound intercalation which is also the subject matter of claims 1-7, 13, 14, and 22 of said Patent.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 4, 2005

Ardin H. Marschel 1/4/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER